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**BEFORE THE BOARD OF PATENT APPEALS
AND INTERFERENCES**

Application Number: 10/738,477

Filing Date: December 17, 2003

Appellant(s): JONES ET AL.

Eugene L. Szczerina
For Appellant

EXAMINER'S ANSWER

This is in response to the appeal brief filed 6/4/2010 appealing from the Office action
mailed 1/12/2010.

(1) Real Party in Interest

The examiner has no comment on the statement, or lack of statement, identifying by name the real party in interest in the brief.

(2) Related Appeals and Interferences

The examiner is not aware of any related appeals, interferences, or judicial proceedings which will directly affect or be directly affected by or have a bearing on the Board's decision in the pending appeal.

(3) Status of Claims

The following is a list of claims that are rejected and pending in the application: 1-18 are pending, 1-16 have been withdrawn and are not under appeal. 17 and 18 are finally rejected and under appeal.

(4) Status of Amendments After Final

The examiner has no comment on the appellant's statement of the status of amendments after final rejection contained in the brief.

(5) Summary of Claimed Subject Matter

The examiner has no comment on the summary of claimed subject matter contained in the brief.

(6) Grounds of Rejection to be Reviewed on Appeal

The examiner has no comment on the appellant's statement of the grounds of rejection to be reviewed on appeal. Every ground of rejection set forth in the Office action from which the appeal is taken (as modified by any advisory actions) is being maintained by the examiner except for the grounds of rejection (if any) listed under the

subheading "WITHDRAWN REJECTIONS." New grounds of rejection (if any) are provided under the subheading "NEW GROUNDS OF REJECTION."

(7) Claims Appendix

The examiner has no comment on the copy of the appealed claims contained in the Appendix to the appellant's brief.

(8) Evidence Relied Upon

2002/0143348	Wallace et al	10-2002
2002/0107330	Pinchuk et al	8-2002

(9) Grounds of Rejection

The following ground(s) of rejection are applicable to the appealed claims:

Claims 17-18 are rejected under 35 U.S.C. 103(a) as being unpatentable over Wallace et al (US 2002/0143348) in view of Pinchuk et al (2002/0107330).

Wallace et al teaches a medical device composed of a support member 2 used as an embolic device (title) which is covered in a polymer that is partly solvated by a liquid agent, after which the surface of the support member 2 is exposed to bodily fluids. *"In certain embodiments, the material (e.g. polymer) to be solvated is coated onto the surface of the device(s)..."* (Paragraph 43) and *"...the liquid agent is capable of solvating polymeric material of the device."* (Paragraph 23). Delivery is done via a catheter, *"...a large catheter is introduced through an entry site in the vasculature"* (Paragraph 46). The tip of the catheter is advanced to the selected site, *"Once the distal end of the catheter is positioned at the site, often by locating its distal end through the use of a radiopaque marker*

*material and fluoroscopy, the catheter is cleared.” (Paragraph 46). The device is then delivered through the catheter, “The device is advanced past the distal end of the catheter and positioned or extruded precisely at the desired treatment site. “ (Paragraph 46), after which the liquid agent is delivered, “*The liquid agent is preferably infused after extrusion...*” (Paragraph 46)*

While Wallace et al substantially discloses the apparatus as claimed, it does not disclose a bioactive agent disposed between the support member and the barrier nor does he teach the polymer is specifically a barrier for the bioactive agent. Pinchuk et al, which is partly drawn to aneurysm fillers, “Preferred medical devices for use in conjunction with the present invention include... composites for aneurysm fillers” (Paragraph 180), does teach a barrier layer of polymers, “In some instances, it may be desirable to temporarily enclose the therapeutic-agent-loaded copolymer to prevent release before the medical device reaches its ultimate placement site.” (Paragraph 183) and “It also may be useful to coat the copolymer of the present invention (which may or may not contain a therapeutic agent) with an additional polymer layer (which may or may not contain a therapeutic agent). This layer may serve, for example, as a boundary layer to retard diffusion of the therapeutic agent and prevent a burst phenomenon whereby much of the agent is released immediately upon exposure of the device or device portion to the implant site.” (Paragraph 204) The polymers taught by Wallace et al such as polyvinylpyrrolidone, polyesters, polyethylene, etc (paragraph 30) are also many the polymers taught by Pinchuk et al. (Paragraph

205) Wallace et al does teach, "*The devices, assemblies, and methods described herein may also include one or more bioactive materials... for example a thrombotic agent...*" (Paragraph 39, emphasis added) Therefore it would have been obvious to one of ordinary skill in the art at the time the invention was made to form a medical device of Wallace et al such that a thrombotic agent as taught by Pinchuk is disposed between a polymer coating and support member because: a) as noted above, Wallace et al teaches the device may include a thrombotic agent, and b) Pinchuk suggests coating with a polymer identical to the polymers of Wallace et al to "...prevent release before the medical device reaches its ultimate placement site." (Paragraph 183)

(10) Response to Argument

Applicant argues that the claimed invention describes an outer barrier that does not release a bioactive agent coated on a medical device until an external agent is applied and is thus not rendered obvious by the art of record since the embolic devices have an outer coating which automatically dissolves in contact with blood. The Examiner believes that one reading Wallace and Pinchuk as a whole would be lead to the claimed invention. Wallace is used as the primary device for a reason. In embodiment 'c' of figure 1, Wallace discloses a polymer coated metal (Paragraph 32); 'a' is the metal and 'b' is the polymer, Wallace thus shows the polymer is on the outside of the metal. Wallace further discloses the same external agent of DMSO (Applicant's specification, page 8 line 15 and Paragraph 17 of Wallace). Wallace also, for all intents and purposes, discloses the same outer barrier layer; Applicant discloses ethylene vinyl

alcohol specifically (Page 8 line 14) and Wallace discloses polyvinyl alcohol. Ethylene vinyl alcohol is simply a species of the genus polyvinyl alcohol. The Examiner misspoke when he said that Wallace does not teach a barrier layer, since the layer of Wallace does not dissolve without the external agent. What was meant is that since Wallace does not teach a bioactive agent, it does not teach placing the bioactive agent of the combined device between the barrier layer and metal device. Regardless, Pinchuk discloses preventing the release of the therapeutic agent before reaching its placement site, such as via a sheath (Paragraphs 183 and 218). Pinchuk also suggests the same materials for the barrier layer as Applicant since paragraph 206 suggests copolymers of the polymers in paragraph 205 and paragraph 205 suggests both polyvinyl alcohol and polyethylene. Thus the combination of Pinchuk and Wallace suggests Applicant's device with respect to a dissolvable outer coating.

Applicant also argues that Wallace does not teach or suggest a bioactive agent disposed on an embolic support member. The Examiner does not dispute this. However, Pinchuk does disclose using therapeutic (paragraph 5) coatings on devices (paragraph 192) that are used in the intra and intervascular systems (Paragrapgh 1). Paragraph 192 discloses coating a metal device with the therapeutic agent and Paragraph 183 discusses using a barrier layer to prevent early release of the drug. Thus one of ordinary skill reading both inventions would be lead to place the therapeutic layer between the metal device and barrier layer of Wallace.

(11) Related Proceeding(s) Appendix

No decision rendered by a court or the Board is identified by the examiner in the Related Appeals and Interferences section of this examiner's answer.

For the above reasons, it is believed that the rejections should be sustained.

Respectfully submitted,

/Bradley J Osinski/

Examiner, Art Unit 3767

Conferees:

/Kevin C. Sirmons/

Supervisory Patent Examiner, Art Unit 3767

/Sue Lao/

Primary Examiner